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| 09/509,237 | 03/20/2000 | Seth D. Rose | 344-P-16-USA | 9691 |

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| EXAMINER |
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FUBARA, BLESSING M

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| ART UNIT | PAPER NUMBER |
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1618

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08/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/509,237

Applicant(s)

ROSE ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt request for continued examination filed under 37 CFR 1.114, amendment and remarks filed 5/16/07. Claim 9 is pending.

Response to Arguments

Previous rejections not reiterated herein are withdrawn.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/16/07 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for octadecyl isocyanate, hydroxysuccinamide, perfluoro-1-octanesulfonyl fluoride, and palmitoyl chloride fatty acid chloride, does not reasonably provide enablement for all compounds containing hydrophobic group. The specification does not enable any person

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skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This is scope of enablement rejection.

It is noted that the specification must teach those of skill in the art how to make and how to use the full scope of the invention as claimed. In re Goodman, 29 USPQ2d at 2013 (Fed. Cir. 1994), citing In re Vaeck, 20 USPQ2d at 1445 (Fed. Cir. 1991). The courts have stated that reasonable correlation must exist between scope of exclusive right to the patent application and scope of enablement set forth in patent application. 27 USPQ2d 1662 Ex parte Maizel.

The Nature of the Invention: The invention is directed to a method of forming a film in situ upon a mucosal tissue that is wet or moist by providing a liquid composition comprising a) volatile solvent, b) water soluble polymer that is selected from the group consisting of carboxymethylcellulose, polyiminodiacetamide and hydroxyethyl cellulose, with the water soluble polymer being capable of attaching to a hydrophobic group through a covalent bonding, and c) a compound containing a hydrophobic group; the composition is then applied to the mucosal tissue.

The Breadth of the claims: The scope of the claims is open to any and all compound containing hydrophobic groups. The scope of the claims is not commensurate with the enabling disclosure where the compound containing hydrophobic groups are octadecyl isocyanate, hydroxysuccinamide, perfluoro-1-octanesulfonyl fluoride, and palmitoyl chloride fatty acid chloride.

The state of the prior art: The prior art is what the prior art knows. There are many compounds containing hydrophobic groups and as the specification points to the artisan in the specification at page 24 that “a hydrophobic group that may principally derive its hydrophobicity

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from a hydrocarbon group, including saturated and unsaturated hydrocarbon.” Compounds such as acetic acid and citric acid have hydrophobic hydrocarbon groups and Pomerantz teaches that these carboxylic acids do not react with hydroxypropylcellulose (column 4, lines 39 and 40 of US 5,081,158 to Pomerantz).

The quantity of Experimentation Needed: Guidance is provided only for octadecyl isocyanate, hydroxysuccinamide, perfluoro-1-octanesulfonyl fluoride, and palmitoyl chloride fatty acid chloride, which are compounds containing hydrophobic groups, and these react with HPC, carboxymethylcellulose, polyvinyl alcohol and polyiminodiacetamide water-soluble polymers. This guidance is not commensurate with the full scope of all compounds containing hydrophobic groups that would react with the recited water-soluble polymers. While the specification further lists some classes of compounds containing hydrophobic groups (page 24 at last paragraph to page 25 at first paragraph), the polymers mentioned are by no means commensurate with the full scope of all compounds that contain hydrophobic groups. The teaching of Pomerantz discussed above introduces an element of unpredictability in at least the interaction of HPC with citric or acetic acid.

Therefore, the quantity of experimentation needed to practice the full scope of the claimed invention is undue and the full scope of the claimed invention has not been enabled by the specification. Scope of enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). In view of the quantity of experimentation necessary to determine the parameters listed above, it would require undue experimentation to practice the full scope of the claim.

Applicant may overcome this rejection by reciting in the claim by Markush language listing the hydrophobic polymers that are enabled such as octadecyl isocyanate,

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hydroxysuccinamide, perfluoro-1-octanesulfonyl fluoride, and palmitoyl chloride fatty acid chloride.

Claim Rejections - 35 USC § 103

4. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over applicants' admitted prior art in view of Alwattari et al. (US 5,874,072).

Applicants in the specification at page 8, lines 8-19, admit of a composition comprising hydrophobe modified hydroxypropyl cellulose, water soluble polymer and ethanol that polymerizes in-situ upon application to body tissue.

However, the claim requires either carboxymethylcellulose or hydroxyethylcellulose. Alwattari discloses that hydroxypropylcellulose and hydroxyethylcellulose are equivalent as film forming polymers (column 3, lines 56-63). Claim 9 2) and 3) read on the hydrophobe modified hydroxypropylcellulose where the hydroxypropylcellulose has been substituted by hydroxyethylcellulose. One film-forming polymer can substitute for another (see equivalency of hydroxypropylcellulose and hydroxyethylcellulose in Alwattari at column 3, lines 56, 61-53 and as described above). The ethanol meets the limitation of volatile solvent. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use hydroxypropylcellulose modified by a compound containing hydrophobic group as the film-forming polymer. It would have been obvious to substitute the hydroxyethylcellulose polymer of Alwattari for the hydroxypropylcellulose in view of the fact that Alwattari teaches hydroxypropylcellulose and hydroxyethylcellulose as equivalent film forming polymers and with

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the expectation that the composition will form a film upon application of the composition to a body tissue.

Response to Arguments

5. Applicant's arguments filed 5/16/07 have been fully considered but they are not persuasive.

Applicant argues that the rejection is inappropriate because a) "one of ordinary skill in the art would not look to Alwattari that relates to aesthetic, external cosmetic products, to achieve a film for normally wet or moist mucosal tissue" and b), "while two substances may be members of the same class, they are not uniformly substitutable," so that the disclosure of Alwattari should not render the present claims obvious. Applicant further argues that c) because externally and internally applied products are judged by different standards, the polymers of Alwattari would not be obvious to use in the wet or moist internal mucosal environment in view of safety considerations and further in view of the consideration that members of the class of film forming polymers disclosed in Alwattari are not always equivalent in all applications.

Response:

Regarding a), it is noted that the rejection is appropriate because Alwattari is relied upon for teaching equivalency of hydroxyethylcellulose and hydroxypropylcellulose as film forming polymers; regarding b), applicant has not factually shown that two polymers that are water-soluble and are film-forming cannot be substitutable; thus in the absence of factual evidence showing that hydroxyethylcellulose cannot be used in place of hydroxypropylcellulose,

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applicant's admitted prior art in view of a teaching that two polymers, hydroxyethylcellulose and hydroxypropylcellulose are both film forming so that the use of one in place of the other is prima facie obvious and expectation for forming film on surfaces is high and predicted in view of the teaching of the prior art. Regarding c), it is noted that the Patent Office is not the FDA and applicant has not provided factual evidence that hydroxyethylcellulose cannot be used as a film forming polymer for moist surfaces. In the absence of factual showing, the applicant's admitted prior art in view of a teaching that two polymers, hydroxyethylcellulose and hydroxypropylcellulose are both film forming so that the use of one in place of the other is prima facie obvious and expectation for forming film on surfaces is high and predicted in view of the teaching of the prior art.

Specifically, Alwattari is relied upon for disclosing that hydroxypropyl cellulose and hydroxyethyl cellulose are both film forming polymer. However, Alwattari's composition comprises water-insoluble polymeric material, water-soluble film forming polymers and optional ingredients such as oils and fats, emulsifiers, waxes, pigments and miscellaneous ingredients such as silica, preservatives, EDTA and imidazolidinyl urea (column 2, lines 10-15 and 20; column 3, lines 27, 55, 60-63; column 4, lines 22, 31, 63; column 5, lines 26, 64; and column 6, line 41). The compound containing a hydrophobic group of claim 9 3) reads on water insoluble polymeric materials such as aromatic diamines, terephthaloyl halides, olefinic polyols, glycidyl derivatives of alkyl esters of unsaturated carboxylic acids, etc (column 2, lines 35-55). Claim 9 is not a process for modification of HEC or carboxymethylcellulose and therefore, the prior art does not have to disclose modification of HEC to meet the claim. Further, the modification process disclosed in the instant specification relies on mixing the polymer with solvent and with

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the compound containing the hydrophobic group (instant Example 1). Mixing of the components is also envisaged in Alwattari in order to form the composition. It is further noted that no specific compound containing hydrophobic group is claimed, which means that any compound having a hydrophobic group is applicable. Alwattari discloses film-forming polymers that are combined with water-insoluble polymers in a composition and Alwattari does not exclude any of the film-forming water-soluble polymers from the composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

